DEPARTMENT OF HEALTH AND HUMAN SERVICES

938010

Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

December 18, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
Ref. KAN 2003-04

Charles L. Vander Ploeg
President/CEO
Vet Pharm, Inc.
392 15th Street, N.E.
P.O. Box 167
Sioux Center, IA 51250

Dear Mr. Vander Ploeg:

Recently an inspection was made of your veterinary drug sales facility located at the above address. This inspection was conducted from September 11 to 13, 2002, by a Food and Drug Administration Investigator from this office who documented sales of prescription drugs for veterinary use that are adulterated within the meaning of Section 501(a)(5) of the Federal Food, Drug, and Cosmetic Act (Act) and misbranded within the meaning of Section 502(f)(1) of the Act.

The drugs "Amoxil Amoxicillin For Oral Suspension" and "Sulfamethoxazole and Trimethoprim Oral Suspension USP" among others, are human drugs that are being dispensed for animal use without the required labeling, including adequate directions for use.

Under Section 512(a)(5), a drug approved for human use may be used in animals if its use or intended use is on the lawful order of a veterinarian and is in compliance with the regulations at 21 CFR Part 530. The human drugs you are dispensing for use in animals are not in compliance with 21 CFR 530.12 because they do not bear the required labeling information.

Because your products do not comply with the applicable regulations, they are unsafe within the meaning of Section 512(a) and are thus adulterated under Section 501(a)(5).

In addition, prescription veterinary drugs intended for extralabel use which you are dispensing are not in compliance with 21 CFR 530.12 because they do not bear the required labeling information. Because these products do not comply with the applicable regulations, they are also unsafe within the meaning of Section 512(a) and thus adulterated under Section 501(a)(5).

Finally, because your products are dispensed without adequate directions for use, they are misbranded under Section 502(f)(1).

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence at any of the established locations within your company. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

The violations listed above are not intended to be all-inclusive. You, as a corporate official of this firm, have a responsibility to insure that all drugs intended for veterinary use, which bear the human or veterinary prescription legend, are sold by you or your firm properly labeled as required.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

Charles W. Sedgwick
District Director
Kansas City District